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| 10/620,686 | 07/17/2003 | Kenneth K. Sokoll | 1038-1266 MIS | 9631 |
| 7590 Michael I. Stewart Sim & McBurney, 6th Floor 330 University Avenue Toronto, ON M5G 1R7 CANADA | | | EXAMINER ALSTRUM ACEVEDO, JAMES HENRY | |
| | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/620,686

Applicant(s)

SOKOLL ET AL.

ExaminerJAMES H. ALSTRUM
ACEVEDO**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71 and 76-85 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 71, 76-79 and 82-85 is/are rejected.
7) ☒ Claim(s) 80-81 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claims 71 and 76-85 are pending. Applicants previously cancelled claims 1-70, 72-75, and 86. Applicants have amended claims 70, 77, and 83-85. Receipt and consideration of Applicants' arguments/remarks submitted on August 11, 2008 are acknowledged. All rejections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments and/or persuasive arguments.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Terminal Disclaimer(s)

The terminal disclaimers filed on August 11, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Nos. (a) 6,042,820 and (b) 6,228,423 have been reviewed and are accepted. The terminal disclaimers have been recorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 71, 76-79, and 82-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Determination of Claim Scope

Claim 71 of the instant application claims an immunogenic composition comprising a particulate carrier having the general formula depicted in said claim. The carrier is a block copolymer (i.e. a specific genus of molecules) having six variable substituents, R₁-R₆, as defined in claim 71.

Review of Applicants' Disclosure

The instant specification does not explicitly define the term immunogen. Immunogen is understood to refer to any molecule that induces an immune response in a living being. Paragraph 3 of Applicants' specification suggests that typical immunogens are attenuated pathogens (e.g. polio virus), killed pathogens (e.g. *Bordetella pertussis*), or immunogenic components of a pathogen (e.g. diphtheria toxoid and hepatitis B surface antigen). Thus, reasonably interpreting the claim language, an immunogen may be a live or dead virus, bacteria, parasite, or any part thereof that induces an immune response.

The instant specification does not depict the chemical structure of any polymeric carrier particle of the claimed invention wherein R₆ is a specific immunogen. On pages 7-8 a polymer

having a similar formula to that depicted in claim 71 is described and depicted, but this polymeric molecule defines R6 as being selected from H, an amine protecting group, a spacer molecule, or a biologically active species. On page 10 a species of the polymer molecule is depicted and described, wherein R6 is selected from H, an amine protecting group, a spacer molecule, or a biologically active species and has a molecular weight of about 5,000 to about 40,000 daltons. It is also noted that on page 9, lines 5-10, Applicants indicate that the invented polymers may contain biologically active moieties such as macrophage stimulators, cell bio-adhesion groups, etc. However, the description on page 9, lines 5-10 is inadequate to clearly describe any particular immunogen, because it does not describe or the point of attachment of the biologically active moiety to the invented polymers. None of Applicants' examples teach how to make polymer particles chemically bound to any immunogen. Applicants' synthetic examples merely teach how to prepare Applicants' invented monomer, polymerize said monomer to obtain homopolymers and copolymers, and how to encapsulate antigens (i.e. immunogens, such as Hin-47 analog) into microparticles comprising the invented polymers.

An Ordinary Skilled Artisan's Determination of Possession/ the State of the Prior Art

Amine protecting groups and the chemistry of attaching such protecting groups are well-known. Thus, the attachment of an amine protecting group to the polymers depicted in instant claim 71 is not beyond the skill of the ordinary artisan and can reasonably be envisaged based on Applicants' disclosure and what is well known in the art. Nonetheless, microparticles comprising the polymer genus described by the formula depicted in Applicants' claim 71, wherein the immunogen is not an amine protecting group cannot be clearly envisaged, because

the ordinary skilled artisan would not know what the ultimate structure of the resulting polymeric molecule would be. Furthermore, given the great variability, complexity, and diversity of what may reasonably be interpreted as being an immunogen (e.g. polio virus) an ordinary skilled artisan would be unable to clearly envisage, which particular species were in Applicants' possession or reduced to practice at the time of the instant invention. It is concluded that Applicants have not adequately described the claimed microparticles, wherein R6 may be any immunogen, such that Applicants have reasonably demonstrated possession of the claimed genus.

The remaining claims are rejected as depending from a rejected claim.

Allowable Subject Matter

Claims 80-81 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 71, 76-79, 82-85 are rejected. Claims 80-81 are objected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616